

REMARKS

The Office action dated May 25, 2010 is acknowledged. According to the Office action, claims 1-15 are pending, claims 5-8, 11 and 15 have been withdrawn and claims 1-4, 9, 10 and 12-14 have been rejected. By the present response, claim 1 has been amended and claims 16-20 have been added. In claim 1, “active substance” has been amended to be more precisely defined as a “pharmaceutically active substance,” support for which may be found in the specification such as at paragraphs [00005] or [000028]. Also in claim 1, the phrase “contains at least one coloured ingredient, or which is colourless...” has been amended to read “contains an ingredient selected from the group consisting of at least one coloured ingredient, and at least one colourless ingredient which is colourless...” for purposes of clarification. Claim 1 has also been amended to recite that the “ingredient” may either be a pharmaceutically active substance (such as supported in the first paragraph of claim 1) or an auxiliary agent (supported by the specification, such as paragraph [00005]).

Support for new claims 16-20 may be found throughout the specification as follows.

- Claim 16 – further clarifies the “lightness colour value” received in claim 1, by specifying that the value is determined by a tristimulus colorimeter (paragraph [000016]).
- Claim 17 – recites the range as recited in the specification at paragraph [000048].
- Claim 18 – recites that the patch is transparent, which is supported by claim 1, 3rd paragraph, 1st alternative.

- Claim 19 – pertains to the embodiment of the present invention where the dye/pigment is incorporated in a transparent backing layer (specification, paragraph [000022]).
- Claim 20 – further clarifies that the medical active substance patch is coloured due to the presence of dyes (s) or pigment(s) (paragraph [000021]).

Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Specification

The Examiner has objected to the specification for using various alleged trademarks without capitalization and/or proper generic terminology. The specification has been amended accordingly, as set forth above. It is also noted that “Naturell B Plv” and “Naturell pulver” are not registered trademarks but rather appear to be trade names of the supplier Cosnaderm. The terms have been labeled accordingly. Withdrawal of this objection is requested.

Information Disclosure Statement

The Examiner states that a legible copy of each cited foreign patent document and non-patent literature publication listed in the information disclosure statement of record has not been filed. Copies of the relevant prior art are enclosed to be entered into the records of the present application.

Rejection of claims 1-4, 9, 10 and 12-14 under 35 U.S.C. 112, first and second paragraphs

The Examiner has rejected claims 1-4, 9, 10 and 12-14 under 35 U.S.C. 112, first

paragraph, as failing to comply with the written description requirement in that the claims contain subject matter which was not described in the specification as to convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. Specifically, the Examiner states that the claims recite “dyes and pigments” but the specification gives no guidance to one of ordinary skill in the art regarding any dyes and pigments except for two art-unknown trademarks/names “Naturell BB PIV” and “Naturell pulver.” In addition, the Examiner states that “dyes and pigments” could encompass a myriad of components and materials, known and unknown, and so the term is only an invitation to experiment regarding dyes and pigments.

The Examiner has also rejected claims 1-4, 9, 10 and 12-14 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nicotine as a pharmaceutically active substance provided in a transdermal patch comprising a Durotak 2052 polymer matrix and PET film having a 15 µm thickness in order to provide transparent or translucent patch as disclosed by the current example, does not reasonably provide enablement for all or any other pharmaceutically active substance, polymer matrix or backing materials of any other thickness.

The Examiner has rejected claims 1-4, 9, 10 and 12-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner states that the claims are confusing because, while the claims recite a transparent or translucent patch, the claims also recite inclusion of dyes and pigments in all the layers of the patch. Thus, the Examiner questions how the patch containing dyes

and pigments is transparent.

Regarding the lightness color value and their measurement, the Examiner states that it is unclear regarding what degree is used to measure 5° to 100°. Thus, the Examiner concludes that the values recited by the present claims are incomplete insofar as they do not specify the frame of reference used to measure them.

The Applicants respectfully disagree with the Examiner's conclusion and request that the rejections be withdrawn.

As noted above, the terms "Naturell BB Plv" and "Naturell pulver" are not registered trademarks. Although the present specification does not describe in detail the two pigments used in the Example, it can be inferred by one skilled in the art that a mixture of two different pigments was used and that different concentrations of this mixture were used. It seems that the pigments were "skin-colored," which is implied by the descriptive term "naturell" and that "plv" stands for "pulver" (which is German for "powder"). Enclosed is the technical specification (dated July 11, 2007) for "656511 Dragocolor Naturel" from the manufacturer Cosnaderm – the same manufacturer as the aforementioned pigments. This product is described as having the appearance of a brown powder (page 4, item 5) and it is composed of a mixture of four different pigments (pigment yellow, pigment red, pigment black and pigment white; items 1.1 – 1.4 on pages 1-3).

Also enclosed is an excerpt from Cosnaderm's current supply program (from www.cosnaderm.com) which also mentions No. 656511 "Dragocolor Naturell" as "pow. Pigment" (i.e., powdered pigment). As the other products shown in that list are described

by their colors (i.e., pink, orange, green, etc.), it implies that the description “naturell” refers to a “brownish” skin color. Thus, the aforementioned allegedly “art unknown trademarks/names” should be understood by one skilled in the art.

Due to the lack of description for dyes and pigments, the Examiner has further questioned whether the Applicant was in possession of the claimed subject matter. However, the Applicant respectfully disagrees since dyes and pigments that are suitable for the preparation in pharmaceutical compositions are generally known to those skilled in the art. Therefore, it is clear that the present invention does not claim dyes and pigments of any kind but rather only such pigments which are generally regarded suitable for use in pharmaceutical compositions. For instance, it is common practice to add dyes or pigments to tablets, capsules or injectable solutions. Thus, it is submitted that it would be clear to one skilled in the art that “dyes and pigments” would be limited to only those that are conventionally employed in the art and not a myriad of compounds and materials.

It is also explained in the specification at paragraph [000024] that the optical inconspicuousness was found to be determined primarily by the concentration of the dyes/pigments, rather than by the nature of these dyes/pigments. Therefore, it is submitted that based on the information provided in the present specification, one skilled in the art would have good reason to expect that the claimed invention could also be practiced by using other kinds of dyes/pigments (i.e., different from the pigments used in the Example of the specification) that are conventional in the art.

Regarding the Examiner’s question as to how the transparent or translucent patch could contain dyes or pigments, it is believed that there is no contradiction in claiming a

patch which contains dyes/pigments and which is, despite the presence of the dyes or pigments, transparent or translucent. "Transparent" is defined as "having the property of transmitting rays of light through its substance; admitting the passage of light through interstices" (Exhibit A). "Translucent" is defined as "permitting light to pass through but diffusing it" (Exhibit B). Both characteristics are defined by the ability to allow light to pass through. Being colored or colorless is irrelevant to transparency or translucency. It is known that objects may be coloured and, at the same time, transparent (e.g., coloured transparent plastic films or coloured window panes, such as in churches). (In fact, color centers (or dye molecules, or "dopants") in a dielectric absorb a portion of the incoming light wave. The remaining frequencies (or wavelengths) are free to be reflected or transmitted and this is how colored glass is produced.) The skilled artisan can easily determine the concentration range of a dye/pigment which produces a transparent colouring without rendering the coloured object opaque (i.e., non-transparent or non-translucent; impenetrable to light) (Exhibit C).

As noted above, the Examiner also states that the specification fails to provide enablement for active substances other than nicotine, etc. However, it is stated in the introductory section of the present specification that active substance patches were known in the art and that it was also known that certain substances used in the manufacture of such patches are coloured or have a tendency to discolor. Therefore, one skilled in the art who is aware of the existence of active substances having the described properties can be expected to use these substances in connection with the present invention, other than nicotine.

Regarding the polymer matrix and backing layer materials, it should also be pointed out that those skilled in the transdermal art are familiar with such materials (as discussed in the introductory section of the present specification).

In the subparagraph of the Office action titled “The state of the prior art,” the Examiner indicated that “the art however does not recognize transparent patch containing dyes or pigments.” This seems to allege that the skilled artisan would not have been enabled to incorporate dyes or pigments into a transparent patch. However, it is submitted that there is no reason to doubt that one skilled in the art should be able to add dyes or pigments to a transparent patch, e.g., to a transparent backing layer of a patch, considering the relative skill of those in the art (i.e., adding dyes or pigments to a pharmaceutical composition is not beyond the standard skill level in the art) and considering that the skilled artisan can easily determine the concentration of a dye/pigment which results in a transparent product. The skilled person, when practicing the present invention, simply has to avoid using excessive amounts of dyes or pigments which would render the patch (or backing layer) opaque.

The Examiner further states that the unpredictability of the art regarding transparent patches comprising dyes and pigments, etc. would be high. However, the Examiner has not indicated exactly which effects would be unpredictable. Apart from dyes or pigments, transparent patches comprising a matrix with matrix polymers, pharmaceutically active ingredients and transparent backing were recognized in the art (see paragraph 2, page 8, of the Office action). In view of the reasons set forth above, it is submitted that adding dyes or pigments to such known transdermal compositions, in

accordance with the present invention, does not cause any particular problems that would require undue experimentation.

In view of the above, it is submitted that the present specification clearly provides sufficient guidance for practicing the presently claimed invention. Based on the exemplary substances set forth in the present specification, the skilled artisan can be expected to modify these exemplary embodiments by using, for instance, other types of pharmaceutically active agents or other dyes or pigments without requiring undue experimentation.

Regarding the rejection under Section 112, second paragraph, the Examiner states that the claims are confusing since they require the patch to be transparent or translucent, while also requiring the inclusion of dyes or pigments. As explained above, these two requirements do not conflict with each other since it is generally known that transparent or translucent materials can also be colored.

Regarding the measurement of lightness color values, the Examiner states that it was unclear what degree is used to measure 5° to 100°. In this regard, it is respectfully submitted that the colorimetric measurement of lightness color values is a well-recognized method in the art and that the numbers 5 and 100 relate to a brightness scale (the vertical axis in the “L, a, b color space; the “degree” symbol may be omitted). For reference, enclosed is a technical brochure that is available from the Techkon homepage (www.techkon.com; service...download...brochures...colorimetry). At the top of page 9, it is explained that L ranges from 0 to 100 (which is presumed to correspond to “degrees” specified in the present application). See, for example, paragraphs [000016] and

[000045] which refer to a colorimeter from Techkon GmbH. Thus, it is submitted that the reference to “5° to 100°” meets the requirements of 35 U.S.C. Section 112, second paragraph.

In view of the above, withdrawal of the rejections under 35 U.S.C. Section 112, first and second paragraphs is appropriate.

Rejection of claims 1-3, 5-7, 9-10, 12-13, 16 and 18-23 under 35 U.S.C. 102(b)

Claims 1-4, 9, 10 and 12-14 have been rejected under 35 U.S.C. 102(b) as being anticipated by DE 10053375 (Degen). The Examiner states in the Office action that Degen discloses a transparent transdermal therapeutic system (TTS) that contains photosensitive active ingredient and that the TTS comprises colorless active ingredients contained in the polymer matrix and has a backing layer. As explained in the Office action, the Examiner concludes that Degen teaches every limitation of present claims 1-4, 9, 10 and 12-14 and thus anticipates the presently claimed invention.

The Applicants respectfully disagree with the Examiner’s conclusion and submit that the present invention as defined in the present claims is patentably distinct from the invention disclosed in the prior art Degen reference. For example, on page 8, subsection 2 of the Office action, it is stated that “the [prior] art does not recognize transparent patch containing dyes or pigments.” Present claim 1 pertains to an active substance patch which is transparent (or translucent) and which contains dyes or pigments. Therefore, it is submitted that the Examiner’s conclusion stating that “all the limitations of the rejected claims are met by the Degen reference” is incorrect based on the Examiner’s other findings of the prior art.

Nevertheless, regarding dyes/pigments, the Examiner states on page 12 of the Office action that the UV absorbers disclosed by Degen have color (white). However, these UV absorbers only appear white when they are present as crystalline powder and they are not capable of coloring (i.e., dyeing) the transdermal therapeutic systems (TTS's) in which they are incorporated. Accordingly, Degen describes these UV absorbers as being "colourless substances" and the TTS is also described as being colourless (claims 1-5). Generally, the term "dye" relates to a substance which can be used to give colour to something (e.g., hair). The colourless UV absorbers described by Degen cannot be regarded as dyes since they cannot be used for dyeing. An illustrative example would be substances such salt or sugar also have a color (white) but cannot be used for dyeing. Therefore, the Examiner's conclusion that the disclosure of a white substance (UV absorber) reads on "dyes or pigments" is incorrect as the UV absorbers are incapable of dyeing or providing pigmentation.

In turn, since the presently claimed patches differ from the patches disclosed by Degen with respect to structure/composition, the Examiner's conclusion that the claimed lightness color value would be inherent to Degen's patch is also incorrect.

In conclusion, it is submitted that Degen fails to teach each and every limitation of the present claims, and therefore the reference fails to anticipate the present invention as set forth in the present claims. Withdrawal of this rejection is respectfully requested.

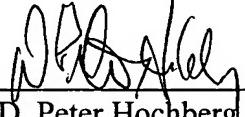
Conclusion

For the foregoing reasons, it is believed that the present application, as amended,

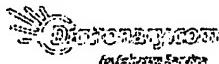
is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the anticipation and obviousness-type rejections be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: May 13, 2010

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trans·par·ent [trans-pair-uht, -par-] [? Show IPA](#)

-adjective

1. having the property of transmitting rays of light through its substance so that bodies situated beyond or behind can be distinctly seen.
2. admitting the passage of light through interstices.
3. so sheer as to permit light to pass through; diaphanous.
4. easily seen through, recognized, or detected: *transparent excuses*.
5. manifest; obvious: *a story with a transparent plot*.
6. open; frank; candid: *the man's transparent earnestness*.
7. Computers . (of a process or software) operating in such a way as to not be perceived by users.
8. Obsolete . shining through, as light.

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[Use transparent in a Sentence](#)[See Images of transparent](#)**Origin:**

1375–1425; late ME < ML *trāspārent-* (s. of *trāspārēns*) showing through (ppr. of *trāspārēre*), equiv. to L *trāns-* trans- + *pārent-* (s. of *pārēns*), ppr. of *pārēre* to appear; see [apparent](#)

-Related forms

trans·par·ent·ly, adverb
trans·par·ent·ness, noun
non-trans·par·ent, adjective
non-trans·par·ent·ly, adverb
non-trans·par·ent·ness, noun
sub-trans·par·ent, adjective
sub-trans·par·ent·ly, adverb
sub-trans·par·ent·ness, noun
un-trans·par·ent, adjective
un-trans·par·ent·ly, adverb
un-trans·par·ent·ness, noun

—Can be confused: [translucent](#), transparent (see synonym note at this entry).

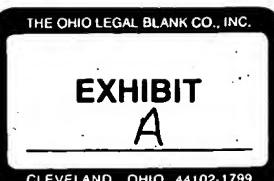
Synonyms

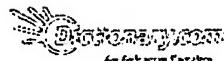
1. clear, pellucid, limpid, crystalline. TRANSPARENT , TRANSLUCENT agree in describing material that light rays can pass through. That which is TRANSPARENT allows objects to be seen clearly through it: *Clear water is transparent*. That which is TRANSLUCENT allows light to pass through, diffusing it, however, so that objects beyond are not distinctly seen: *Ground glass is translucent*.

Antonyms

1. opaque. 6. secretive.

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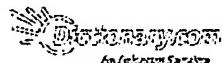
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— adj

allowing light to pass through partially or diffusely;
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O-pa-que [oh-peyk] [Show IPA](#) **adjective, noun, verb,**
 o-pa-qued, o-pa-qu-ing.

-adjective

1. not transparent or translucent; impenetrable to light; not allowing light to pass through.
2. not transmitting radiation, sound, heat, etc.
3. not shining or bright; dark; dull.
4. hard to understand; not clear or lucid; obscure: *The problem remains opaque despite explanations.*
5. dull, stupid, or unintelligent.

-noun

6. something that is opaque.
7. *Photography*. a coloring matter, usually black or red, used to render part of a negative opaque.

-verb (used with object)

8. *Photography*. to cover up blemishes on (a negative), esp. for making a printing plate.
9. to cause to become opaque.

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1375–1425; late ME *opake* < L *opacus* shaded

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-Synonyms

1. murky, cloudy, muddy.

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World English Dictionary

opaque (ə'peɪk) [?adj](#)

-adj

1. not transmitting light; not transparent or translucent
2. not reflecting light; lacking lustre or shine; dull

